

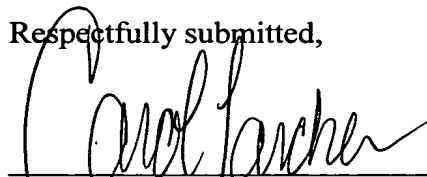
Election with Traverse

Applicants hereby elect the claims of Group I with traverse.

Discussion of Requirement for Restriction

There are two requirements for a proper requirement for restriction between patentably distinct inventions. The inventions must be independent or distinct as claimed, and there must be a serious burden on the examiner if restriction is not required. M.P.E.P. § 803. Consequently, as set forth in M.P.E.P. § 803, "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." In the case at hand, the Office alleges that each group is directed to a distinct goal, involves material distinct steps, and generates distinct functions and effects, and that it would be unduly burdensome to search and examine both groups together. While Applicants agree with the Office that *ex vivo* and *in vivo* methods are, in fact, distinct, at issue is whether or not it would present an under burden on the Office to search and examine both groups of claims together. In this regard, Applicants point out that both groups of claims involve contacting a cell with (i) a genetic construct comprising AAV ITRs and a DNA encoding a polypeptide or genetic transcript of interest operably linked to a promoter and (ii) either an AAV Rep protein-encoding genetic construct or AAV Rep protein. In view of this, Applicants respectfully submit that searching one group would likely uncover references that the Office would consider in examining the claims of the other group and *vice versa*. Therefore, Applicants request the withdrawal of the restriction requirement.

Respectfully submitted,



Carol Larcher, Reg. No. 35,243  
One of the Attorneys for Applicants  
LEYDIG, VOIT & MAYER, LTD.  
Two Prudential Plaza, Suite 4900  
Chicago, Illinois 60601-6780  
(312) 616-5600 (Telephone)  
(312) 616-5700 (Facsimile)

Date: January 21, 2003

In re Appln. of Kotin et al.  
Application No. 09/922,327

**CERTIFICATE OF MAILING**

I hereby certify that this RESPONSE TO RESTRICTION REQUIREMENT (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

Date: January 21, 2003

Kathleen M. Grant

M:\Clients\NIH\Amd\211600rrr.doc



THE PATENT AND TRADEMARK OFFICE IS RESPECTFULLY REQUESTED TO PLACE ITS STAMP ON THIS POSTAL CARD AND PLACE IT IN THE OUTGOING MAIL TO SHOW THE FOLLOWING PAPERS HAVE BEEN RECEIVED.

Attorney Docket No. 211600  
DHHS Ref. No.: E-225-94/1  
In Re Application of: Kotin et al.  
U.S. Patent Application: 09/992,327  
Filed: August 3, 2001  
For: LIPID VESICLES CONTAINING ADENO-ASSOCIATED VIRUS REP PROTEIN-  
FOR TRANSGENE INTEGRATION AND GENE THERAPY

Enclosed: Form PTO-1083 (1 pg in duplicate); Response to Restriction Requirement  
with Certificate of Mailing (3 pgs.); and postcard.

Mailed: January 21, 2003  
CL/kng

RECEIVED

FEB 04 2003

TECHNOLOGY CENTER R3700

TECH CENTER 1600/2900

MAR 12 2003

RECEIVED